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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/682,101	10/09/2003	Daniel F. Justin	ZIM0403	9213
7590 John F. Hoffman, Esq. BAKER & DANIELS LLP Suite 800 111 East Wayne Street Fort Wayne, IN 46802			EXAMINER PRIDDY, MICHAEL B	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 08/22/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/682,101

Applicant(s)

JUSTIN ET AL.

Examiner

Michael B. Priddy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 and 34-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 20060213 & 20060321 & 20031009.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of invention II, claims 11-33, in the reply filed on 05/19/2006 is acknowledged.

Priority

A later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 10/132,668, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The prior-filed application provides support for an implant but not for the tools to insert, remove, assemble or disassemble the implant.

The disclosure of the prior-filed application, Application No. 10/369,331, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The prior-filed application

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provides support for an implant and an assembly/disassembly device of design different from that of the claims presently under consideration.

For the purposes of application of prior art, Applicant will be entitled to the actual filing date of the present application, 10/09/2003.

Claim Objections

Claims 19-29 are objected to because of the following informalities. Appropriate correction is required.

There is an inconsistency between the language of claim 19 and that of claim 23 dependent thereon, thus making the scope of the claim unclear. In the preamble of claim 19, line 1, applicant recites "A instrument" with the tibial tray being only functionally recited, i.e. "for gripping a tibial tray component...", thus indicating that the claim is directed to the subcombination, "An instrument". However, in claim 23, lines 1-2, Applicant positively recites the tibial tray as part of the invention, i.e. "the tibial tray component further includes a dovetail mating surface", thus indicating that the combination, instrument and tibial tray, is being claimed. As such, it is unclear whether Applicant intends to claim the subcombination or combination. Applicant is hereby required to indicate to which, combination or subcombination, the claims are intended to be directed, and amend the claim such that the language thereof is consistent with this intent. For examination purposes claims 19-24 will be considered as being drawn to the subcombination, the instrument.

There is an inconsistency between the language of claim 25 and that of claim 26 dependent thereon, thus making the scope of the claim unclear. In the preamble of claim 25, line 1, applicant recites "A disassembly tool" with the modular tibial knee implant including a tibial tray component being only functionally recited, i.e. "for disassembling a modular tibial knee implant including a tibial tray component...", thus indicating that the claim is directed to the subcombination, "A disassembly tool". However, in claim 26, lines 1-2, Applicant positively recites the tibial tray as part of the invention, i.e. "the bearing locking mechanism includes a tray dovetail surface on the tibial tray", thus indicating that the combination, the disassembly tool and tibial tray, is being claimed. As such, it is unclear whether Applicant intends to claim the subcombination or combination. Applicant is hereby required to indicate to which, combination or subcombination, the claims are intended to be directed, and amend the claim such that the language thereof is consistent with this intent. For examination purposes claims 25-27 will be considered as being drawn to the subcombination, the disassembly tool.

There is an inconsistency between the language of claim 28 and that of claim 29 dependent thereon, thus making the scope of the claim unclear. In the preamble of claim 28, line 1, Applicant recites "An assembly tool" with the tibial keel being only functionally recited, i.e. "for assembling a modular tibial knee implant including... a tibial keel component...", thus indicating that the claim is directed to the subcombination, "An

assembly tool". However, in claim 29, lines 1-2, Applicant positively recites the tibial keel as part of the invention, i.e. "the second member passes through an opening in the tibial keel component", thus indicating that the combination, the assembly tool and tibial keel, is being claimed. As such, it is unclear whether Applicant intends to claim the subcombination or combination. Applicant is hereby required to indicate to which, combination or subcombination, the claims are intended to be directed, and amend the claim such that the language thereof is consistent with this intent. For examination purposes claims 28-29 will be considered as being drawn to the subcombination, the assembly tool.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11-20, 24, 30 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmitt (US 6,311,589). Schmitt teaches an instrument for gripping a tibial keel or tray component of a modular keel and tray assembly, the keel component having a first end and a second end, the keel component being configured for insertion of the second end into a tibial bone, the instrument comprising: a handle 16; and an attachment mechanism for connecting the instrument to the keel such that the handle 16 extends outwardly from the keel component to provide a grip for manipulating the

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keel component; the attachment mechanism connects the instrument to the keel component in a reproducible known orientation such that the orientation of the handle 16 indicates the orientation of the keel component even when the keel component is not itself visible; wherein the attachment mechanism further comprises a first jaw 20 attached to the handle 16; and a second jaw 19 attached to the handle 16, the jaws being movable relative to one another to clamp the keel component; therein the attachment mechanism further comprises an actuator 15; a link 13 connecting the actuator 15 to the jaws, the actuator 15 being movable to cause the jaws to move between a closed position in which they are relatively close together and an open position in which they are relatively further apart, the actuator, link and jaws having a point of singularity beyond which further movement of the actuator results in the jaws locking onto the keel in the closed position; the attachment mechanism connects the handle 16 to the first end of the keel component such that upon insertion of the second end of the keel component into the tibial bone, at least one of the attachment mechanism and the handle 16 abut the tibial bone and prevent the first end of the keel component from being fully inserted into the tibial bone; and a cover 25 positionable over a portion of the keel component to shield the portion of the keel component from contamination while the keel component is manipulated into position.

Concerning the limitations of claim 30, Schmitt also teaches a first handle 16, an attachment mechanism 19, a second handle 17 and a second attachment mechanism 20.

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Claims 19 and 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Guilliams (US 4,318,316). Guilliams teaches an instrument capable of gripping a tibial tray component of a modular keel and tray assembly, the tray component having a top and a bottom, the tray component being configured for assembly to the keel component, the instrument comprising: a handle 13; and an attachment mechanism 12/12a for connecting the instrument to the tray such that the handle extends outwardly from the tray component to provide a grip for manipulating the tray component; wherein the attachment mechanism 12/12a further comprises a plurality of adapters 40b, 40c each connectable to the handle 13, and each adapter 40b, 40c connectable to one of a plurality of differently configured tibial tray components such that a common handle can be used with a plurality of differently configured tibial tray components; wherein the adapters include dovetail mating surfaces (the profile shape of the combination of elements 30 and 32) capable of engaging a dovetail mating surface of a tibial tray component.

Claims 25, 28 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Meulink et al. (US 6,238,435). Meulink et al. teach an assembly/disassembly tool capable of assembling and disassembling a modular tibial knee implant including a tibial tray component and a tibial keel component, the tibial tray component and the tibial keel component forming a male/female junction between them, the tibial tray component having a bearing locking mechanism, the tool comprising:

A longitudinal axis; a first member 38 engagable with a bearing locking mechanism in axial first force transmitting relationship; a second member 46 engageable with the first member in axial second force transmitting relationship; a third member 24 engageable with the tibial keel component in axial third force transmitting relationship, the third force opposing the first; and a handle assembly engaging the second and third members, the handle assembly 20 operative to move the second member 46 relative to the third member 24 along the axis to apply opposing forces to the first 38 and third members 24 to move the tibial tray component and the tibial tray component out of male/female seating arrangement; wherein the second member is capable of passing through an opening in a tibial keel component in order to engage a tibial stem component.

Claims 25 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Bauer (US 5,361,782). Bauer teaches an assembly/disassembly tool capable of assembling and disassembling a modular tibial knee implant including a tibial tray component and a tibial keel component, the tibial tray component and the tibial keel component forming a male/female junction between them, the tibial tray component having a bearing locking mechanism, the tool comprising:

A longitudinal axis; a first member 18 engagable with a bearing locking mechanism in axial first force transmitting relationship; a second member 12 engageable with the first member in axial second force transmitting relationship; a third member 14 engageable with the tibial keel component in axial third force transmitting

relationship, the third force opposing the first; and a handle assembly 16 engaging the second and third members, the handle assembly 16 operative to move the second member 12 relative to the third member 14 along the axis to apply opposing forces to the first 18 and third members 14 to move the tibial tray component and the tibial tray component out of male/female seating arrangement; wherein the bearing locking mechanism includes a tray dovetail surface on the tibial tray and the first member is a separate component from the second member having a complimentary dovetail surface matingly engageable with the tray dovetail surface, the second member being engageable with the first member after the first member is engaged with the tibial tray, the second member locking the first member in position on the tibial tray.

Claims 30, 32 and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Keller (US 2003/0229355 A1). Keller teaches a tibial keel holder and tibial tray holder combination, the tibial keel holder being engageable with a tibial keel component of a modular tibial implant and the tibial tray holder being engageable with a tibial tray component of a modular tibial implant, the tibial keel component and tibial tray component forming a male/female junction between them, the combination comprising: a tibial keel holder 52a including a first handle and an attachment mechanism for connecting the instrument to the tibial keel component in a reproducible known orientation; and a tibial tray holder 52b including a second handle and an attachment mechanism for connecting the instrument to the tibial tray component in a reproducible known orientation, the first and second handles forming a predetermined angle between

them to give a visual indication of tray-to-keel rotational alignment; further comprising an assembly tool 31 for moving the tibial tray component and the tibial keel component into male/female seating arrangement, the assembly tool being engageable with the tibial tray component and the tibial keel component while the tibial tray holder is holding the tibial tray; wherein the assembly tool passes through an opening in a tibial tray holder to engage the tibial tray component and the tibial keel component while the tibial tray holder is holding the tibial tray.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bauer.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the assembly of Bauer having a plurality of first members 18, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael B. Priddy whose telephone number is 571-272-2243. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael B. Priddy

Michael B. Priddy
August 17, 2007

Cris Rodriguez

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